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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,522	03/29/2002	Francoise Vinet	220680USOPCT	2382
22850	7590	04/13/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,522	Applicant(s) VINET ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 84 is/are objected to.
- 8) ☒ Claim(s) 54-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/1/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is responsive to the Amendment received on December 28, 2004.

Preliminary Remark

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

Information Disclosure Statement

It appears that the Adelhelm et al. reference cited in the IDS received on July 3, 2002 contained a typographical error. The reference is cited from SPIE, 1996, vol. 2629, pages 325-332 and **not** from Biomedical Optoelectronics in Clinical Chemistry and Biotechnology.

The typographical error has been corrected and the signed copy of the PTO-1449 is attached hereto.

Specification

All objections to the specification made in the Office Action mailed on September 28, 2004 is withdrawn in view of the Amendment received on December 28, 2004.

Claim Interpretation

The preamble of claim 54 recites the term, "unmarked molecules" while all of its dependent claim recite the term, "the" or "said" "molecule." For the purpose prosecution, any recitation of "the" or "said" "molecules" is considered to be "unmarked molecule(s)" of claim 54.

Claim Objections

Claim 84 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 83 serves as an independent claim for claim 84. Claim 83, characterizes the immobilized oligonucleotides by a method of claim 54 (this dependency is indefinite as will be addressed below) which has specific limitation. However, claim 84 is drawn to a method which generically analyzes the immobilized oligonucleotides, broadening the scope of the claim.

Claim Rejections - 35 USC § 112

The rejection of claims 14-53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on September 28, 2004 is withdrawn in view of the Amendment received on December 28, 2004.

New Grounds – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite because while the preamble of the method recites that the method is for “characterizing, quantifying, mapping or analyzing” unmarked molecules, the final step of the method only recites that the method “detects the molecules, rendering the claims confusing as to how the method is to achieve characterizing, quantifying, mapping aspects of the method.

Claims 55-86 are indefinite by way of their dependency on claim 54.

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Claims 60 and 61 contain improper Markush claim language. MPEP 2173.05(h)(I)

discusses proper language format when claiming in Markush format:

“One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925)” (emphasis added)

Claims 60 and 61 recite the conjunction, “or” rather than the required “and.”

Correction is required.

Claim 83 is indefinite because claim 83 dependent on claim 54 but is drawn to a different method – *i.e.*, method for synthesizing an oligonucleotide on a solid substrate. Hence, claim 83 cannot further limit claim 54 which is drawn to a method of analyzing a molecule on solid support, the claim is in how the two methods are performed together.

Claim 85 is also rejected for analogous reasons as above.

Claims 84 and 86 are indefinite by way of their dependency on claims 83 and 85 (respectively).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving the use of light source, wherein said light source is 275 nm and 266 nm, does not reasonably provide enablement for a method involving the use of a light source, wherein said light source produces light of any wavelength. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

(D) Nature of the Invention: The instant invention requires that the light from the excitation source be absorbed by the nitrogenous base or nucleic acid, producing a deviation of probe beam due to the temperature rise in the absorbent sample (page 9, lines 3-9 and 21-27).

(E) State of Prior Art: Giese (U.S. Patent No. 5,952,654) discloses that a light of wavelength 355 nm will not be absorbed by DNA (column 9, lines 47-49).

One of ordinary skill in the art would not be able to practice the invention commensurate in scope of the claims because the claimed scope embodies the use of light source producing wavelengths which are not absorbed by DNAs (or nucleic acids), the DNAs of which are made of nitrogenous bases.

Claim Rejections - 35 USC § 102

The rejection of claims 14-53 under 35 U.S.C. 102(b) as being anticipated by Adelhelm et al. (SPIE, 1996, vol. 2629, pages 325-332), made in the Office Action mailed on September 28, 2004 is withdrawn in view of the Amendment received on December 28, 2004, canceling claims 14-53.

Necessitated by Amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Adelhelm et al. (SPIE 1996, vol. 2629, pages 325-332).

The rejection, while being applied under the same rationale as applied by the previous examiner of record, is made as being necessitated by amendment as Applicants have canceled previously rejected claims.

Applicants' response received on December 28, 2004 have been fully considered but they are not found persuasive.

The argument is based on the interpretation of the claim term, "unmarked molecules." Applicants contend that the method of prior art employ DNA/intercalator-sample (page 10, bottom paragraph, Response) and thus different from the instant method which conducts the method "without using any marker."

This argument is not found persuasive for the following reasons.

According to MPEP 2106(II)(C), claims are given their broadest reasonable interpretation:

"Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. > E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims

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unnecessarily).< In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

The claims as amended is drawn to a method which characterizes unmarked molecules fixed on a support. The term, "unmarked" does not find an explicit definition in the specification so as to exclude the method disclosed by Adelhelm et al. The DNA being employed by Adelhelm et al., in a sense, does not use marked molecules as the DNA is not covalently linked to a marker (intercalator). If Applicants mean by reciting that a molecule is unmarked, an explicit and unambiguous claim language should be employed to mean that the method of characterizing, quantifying, mapping or analyzing is conducted without any labels or markers.

Claims 83-86 are rejected under 35 U.S.C. 102(b) as being anticipated by McGall (U.S. Patent No. 5,843,655, issued December 1, 1998).

The instant rejection is necessitated by the instant amendment, wherein the dependency of claims 83-86 on claim 54 is indefinite.

McGall discloses a method of synthesizing an array of oligonucleotides on a substrate, said method comprising the steps of:

- a) coupling a nucleotide monomer to a solid substrate (column 2, lines 6-17);
- b) analyzing the synthesized array for the efficiency of the synthesis (column 2, line 18-20).

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With regard to claim 84, McGall discloses the step of repeating the addition of monomers (nucleotide) onto the immobilized monomer (column 2, lines 12-14; Figure 1).

Therefore, McGall anticipates the invention as claimed.

Double Patenting

The provisional rejection of claims 14-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-39 of copending Application No. 10/089,164, made in the Office Action mailed on September 28, 2004 is withdrawn in view of the Amendment received on December 28, 2004, canceling the claims.

Necessitated by Amendment

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of ***U.S. Patent No.*** 6,884,582 (previously claims 14-39 of copending Application No. 10/089,164, recently allowed and issued as a U.S. Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

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The instant rejection is being made in view of the fact that Applicants canceled the previously pending and rejected claims and submitted new claims, said new claims not being patentably distinguishable from that which is claimed in the '164 application under the same reasons set forth the Office Action mailed on September 28, 2004.

Applicants are advised that only a Terminal Disclaimer can overcome the instant rejection as the rejection is no longer provisional and the claims are obvious over each other.

Conclusion

No claims are allowed.

Applicants are advised that a co-pending application, serial no. 11/019,266, claims 13-24 might be subject to obviousness double patenting rejection upon the amendment of the instant claims. Applicants are advised to file a terminal disclaimer in their response, should Applicants determine that claims would be subject to such rejection.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

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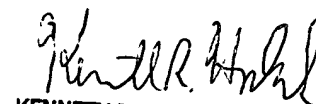
Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
4/8/05

YOUNG J. KIM
PATENT EXAMINER

yjk



KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

4/11/05